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EXAMINER

SHIBUYA, M

ART UNIT

PAPER NUMBER

1635

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/310,844

Applicant(s)
ECKER ET AL.

Examiner
Mark L. Shibuya

Group Art Unit
1635



☒ Responsive to communication(s) filed on Jan 23, 2001

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-113 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-113 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-20, 31, 33, and 34, drawn to an RNA and a purified and isolated RNA comprising a joined sequence of at least sixty-two but not more than seventy nucleotides comprising a secondary structure defined by: five nucleotides forming a first side of a first double stranded region; four nucleotides forming a first end loop region; five nucleotides forming a second side of said first double stranded region; three nucleotides forming a first side of a first internal loop region; five nucleotides forming a first side of a second double stranded region; one nucleotide forming a first side of a second internal loop region; six nucleotides forming a first side of a third double stranded region; eight nucleotides forming a second end loop region; six nucleotides forming a second side of said third double stranded region; one nucleotide forming a second side of said second internal loop region; five nucleotides forming a second side of said second double stranded region; two nucleotides forming a second side of said first internal loop region; three nucleotides forming a first side of a fourth double stranded region; five nucleotides forming a third end loop region; and three nucleotides forming a second side of said fourth double stranded region; variations thereof; wherein said RNA comprises a portion of interleukin-2 RNA and a portion of the 3'UTR of

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interleukin-2 mRNA; SEQ ID NOs: 16 and 17; classifiable in class 536, subclasses 23.1, 24.5.

- II. Claims 21-30, 32, drawn to an *in silico* RNA comprising a joined sequence of nucleotides comprising a secondary structure defined by: five nucleotides forming a first side of a first double stranded region; four nucleotides forming a first end loop region; five nucleotides forming a second side of said first double stranded region; three nucleotides forming a first side of a first internal loop region; five nucleotides forming a first side of a second double stranded region; one nucleotide forming a first side of a second internal loop region; six nucleotides forming a first side of a third double stranded region; eight nucleotides forming a second end loop region; six nucleotides forming a second side of said third double stranded region; one nucleotide forming a second side of said second internal loop region; five nucleotides forming a second side of said second double stranded region; two nucleotides forming a second side of said first internal loop region; three nucleotides forming a first side of a fourth double stranded region; five nucleotides forming a third end loop region; and three nucleotides forming a second side of said fourth double stranded region; variations thereof; wherein said RNA comprises a portion of interleukin-2 RNA and a portion of the 3'UTR of interleukin-2 mRNA; SEQ ID NO: 17; classifiable in classes 536, 702, subclasses 23.1, 24.5 and 19, 27, respectively.

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- III. Claims 35-41, 42-48, 56, 58, 59, drawn to an RNA and a purified and isolated RNA comprising a joined sequence of at least thirty-two but not more than seventy nucleotides comprising a secondary structure defined by: five nucleotides forming a first side of a first double stranded region; one nucleotide forming a first side of a first internal loop region; six nucleotides forming a first side of a second double stranded region; eight nucleotides forming a first end loop region; six nucleotides forming a second side of said second double stranded region; one nucleotide forming a second side of said first internal loop region; and five nucleotides forming a second side of said first double stranded region; variations thereof; wherein said RNA comprises a portion of interleukin-2 RNA and a portion of the 3'UTR of interleukin-2 mRNA; SEQ ID NOs: 18 and 19; classifiable in class 536, subclasses 23.1, 24.5.
- IV. Claims 49-55, 57, drawn to an *in silico* RNA comprising a joined sequence of nucleotides comprising a secondary structure defined by: five nucleotides forming a first side of a first double stranded region; one nucleotide forming a first side of a first internal loop region; six nucleotides forming a first side of a second double stranded region; eight nucleotides forming a first end loop region; six nucleotides forming a second side of said second double stranded region; one nucleotide forming a second side of said first internal loop region; and five nucleotides forming a second side of said first double stranded region; variations thereof;

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wherein said RNA comprises a portion of interleukin-2 RNA and a portion of the 3'UTR of interleukin-2 mRNA; SEQ ID NOs: 18; classifiable in classes 536, 702, subclasses 23.1, 24.5 and 19, 27, respectively.

- V. Claims 60-66, 67-73, 81, 83-86, drawn to an RNA and a purified and isolated RNA comprising a joined sequence of at least forty-three but not more than seventy nucleotides comprising a secondary structure defined by: six nucleotides forming a first side of a first double stranded region; three nucleotides forming a first side of a first internal loop region; six nucleotides forming a first side of a second double stranded region; four nucleotides forming a first end loop region; six nucleotides forming a second side of said second double stranded region; two nucleotides forming a second side of said first internal loop region; six nucleotides forming a second side of said first double stranded region; one nucleotide forming a bulge between said first double stranded region and a third double stranded region; two or four nucleotides forming a first side of a third double stranded region; three nucleotides forming a second end loop region; and two or four nucleotides forming a second side of said third double stranded region; variations thereof; wherein said RNA comprises a portion of interleukin-2 RNA and a portion of the 3'UTR of interleukin-2 mRNA; SEQ ID NOs: 20-22; classifiable in class 536, subclasses 23.1, 24.5.

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- VI. Claims 74-80, 82, drawn to an *in silico* RNA comprising a joined sequence of nucleotides comprising a secondary structure defined by: six nucleotides forming a first side of a first double stranded region; three nucleotides forming a first side of a first internal loop region; six nucleotides forming a first side of a second double stranded region; four nucleotides forming a first end loop region; six nucleotides forming a second side of said second double stranded region; two nucleotides forming a second side of said first internal loop region; six nucleotides forming a second side of said first double stranded region; one nucleotide forming a bulge between said first double stranded region and a third double stranded region; two or four nucleotides forming a first side of a third double stranded region; three nucleotides forming a second end loop region; and two or four nucleotides forming a second side of said third double stranded region; variations thereof; wherein said RNA comprises a portion of interleukin-2 RNA and a portion of the 3'UTR of interleukin-2 mRNA; SEQ ID NO: 20; classifiable in classes 536, 702, subclasses 23.1, 24.5 and 19, 27, respectively.
- VII. Claims 87-100, 108, 110, 111-113, drawn to an RNA and a purified and isolated RNA comprising a joined sequence of at least twenty-nine but not more than seventy nucleotides comprising a secondary structure defined by: five nucleotides forming a first side of a first double stranded region; four nucleotides forming a first side of a first end loop region; five nucleotides forming a second side of said

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first double stranded region; two nucleotides forming a bulge between said first double stranded region and a second double stranded region; five nucleotides forming a first side of a second double stranded region; three nucleotides forming a second end loop region; and five nucleotides forming a second side of said second double stranded region; variations thereof; wherein said RNA comprises a portion of interleukin-2 RNA and a portion of the 3'UTR of interleukin-2 mRNA; SEQ ID NOs: 23-25; classifiable in class 536, subclasses 23.1, 24.5.

- VIII. Claims 74-80, 82, drawn to an *in silico* RNA comprising a joined sequence of nucleotides comprising a secondary structure defined by: five nucleotides forming a first side of a first double stranded region; four nucleotides forming a first side of a first end loop region; five nucleotides forming a second side of said first double stranded region; two nucleotides forming a bulge between said first double stranded region and a second double stranded region; five nucleotides forming a first side of a second double stranded region; three nucleotides forming a second end loop region; and five nucleotides forming a second side of said second double stranded region; variations thereof; wherein said RNA comprises a portion of interleukin-2 RNA and a portion of the 3'UTR of interleukin-2 mRNA; SEQ ID NOs: 23; classifiable in classes 536, 702, subclasses 23.1, 24.5 and 19, 27, respectively.

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2. The inventions are distinct, each from the other because of the following reasons:

3. The inventions of Groups I, III, V, and VII are unrelated to the inventions of Groups II, IV, VI, and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together have different modes of operation, different functions, and different effects because the inventions of Groups II, IV, VI, and VIII are drawn to *in silico* RNA, and the inventions of Groups I, III, V, and VII are drawn to actual molecules of RNA.

4. The inventions of Groups I, III, V, and VII are each unrelated, one to other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together have different modes of operation, different functions, and different effects because they have different molecular structures and nucleotide sequences.

5. The inventions of Groups II, IV, VI, and VIII are each unrelated, one to other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together have different modes of operation, different functions, and different effects because they are *in silico* representations of different molecular structures and nucleotide sequences.

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6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Nucleotide and/or Amino Acid Sequence Disclosure

10. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below. Applicant is required to comply with the corrections for the sequence listing as per above as part of a complete response to this official action.

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11. Applicants disclose a nucleotide sequence in claims 81-83 that must be identified by a SEQ ID number, pursuant to 37 CFR 1.821(d), which states: "Where the description or claims of a patent application discuss a sequence listing that is set forth in the 'Sequence Listing' in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application."

a. Applicant has amended these claims in the Amendment filed 1/23/01 to recite the sequence identifier "SEQ ID NO:20". However, claims 81-83 recite the limitation "N(or absent)N(or absent)". If one or both of said "N's" are absent, then SEQ ID NO:20 does not accurately list the nucleotide sequence. In this situation, "N" is taken to mean a nucleotide and cannot represent the absence of a nucleotide. This violation of the sequence rules has a material effect on the searching for prior art of the claimed sequences, because two sequences claimed are not provided with SEQ ID. Applicant must either delete the limitation "N(or absent)N(or absent)" or provide SEQ ID for the sequences identifiers in the claims, wherein said sequence identifiers recite the sequence when one and both "N's" are absent. If applicant chooses to provide SEQ ID for the sequences wherein one and both "N's" are absent, applicant must make sure that the paper copy of the Sequence Listing and the computer readable form would be correct. If the Sequence Listing and/or the computer readable form would not recite SEQ ID for the sequences wherein one and both "N's" are absent, applicant must furnish a corrected paper copy of the Sequence Listing, a corrected computer readable form, and a statement that the

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content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mark L. Shibuya (SRC)*, whose telephone number is (703) 308-9355, and/or to the patent analyst, *Katrina Turner*, whose telephone number is (703) 305-3413.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader* may be reached at (703) 308-0447.

14. Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is (703) 308-0196.

Mark L. Shibuya
Patent Examiner
Technology Center 1600
April 10, 2001



JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
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